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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/876,812 06/17/97 DOUGLAS J 018176-070 <sup>KM</sup>

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EXAMINER

PHAM, M

ART UNIT

PAPER NUMBER

1641 <sup>20</sup>

DATE MAILED:

01/04/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary****Application No.**

08/876,812

**Applicant(s)**

DOUGLAS ET AL.

**Examiner**

Minh-Quan K. Pham

**Art Unit**

1641

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 52-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 52-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

The amendment filed October 17, 2000, has been entered as Paper No. 19.

### *Claim Status*

Claims 1-16 and 52-68 are pending. Claims 67-68 are added in Paper No. 19.

### *Specification*

The objection to the title of the invention is withdrawn in light of amendment presented in Paper No. 19.

### *Claim Rejections - 35 USC § 112*

Claims 60-66 and 68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is withdrawn for claim 61 in light of argument presented in Paper No. 19. The rejection is maintained for claims 60 and 62-66.

The claims are drawn to a morphology-improving coating which includes conductive and non-conductive materials. Because the specification only discloses non-conductive, morphology-improving material, the claim is broader than the teaching of the specification. Therefore, the claim contains new matter (namely a conductive, morphology-improving material) that is not disclosed in the original specification.

Claims 52-68 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element at least a reagent capable of reacting with the analyte in the fluid sample to produce a measurable electrical change and configuration of electrodes in the conductor layer. The rejection is maintained.

It is not clear how the apparatus of claims 52-68 can be used as an electrochemical test device, because the device, as claimed, are drawn to a substrate with a coating layer and a amorphous semiconductor layer. Further, because it is not clear how the claimed device can function as an electrochemical test device, applicants have failed to particularly point out and distinctly claim the invention. Therefore, the rejection of claims 52-66 under 35 U.S.C. 112, second paragraph, is maintained.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-16 and 52-66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Ovahinsky et al. (US 4,217,374). The rejection is withdrawn for claims 52-59, because Diebold et al. do not teach that the substrate is a metallic material. The rejection is maintained for claims 1-16 and 60-66.

***Allowable Subject Matter***

Claims 52-59 and 67 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action. To overcome the rejection the device should include at least electrodes configuration and reagents to detect analyte.

***Response to Arguments***

In response to applicants' argument that Diebold et al. discloses rigid construction which is not capable of being roll-processed, applicants are reminded that this is only one aspect of the disclosure of Diebold et al. In another aspect, Diebold et al. clearly teach a flexible construction in column 6, line 35-39. Further, Diebold et al. also teach the use of MYLAR<sup>TM</sup> as a substrate (see column 5, lines 62-67). MYLAR<sup>TM</sup> is a flexible film manufactured by DuPont.

Applicants also argued that Diebold et al. do not disclose an intervening coating between the conductor and the substrate. It is clear from columns 3, lines 58-65, that Diebold et al. disclose the use of a thin anchor layer to increase adhesion between the support material and the electrically conducting material. It would have been clear to one of ordinary skill in the art that such thin anchor layer usually involve surface morphology-improving. Further, in column 4, lines 5-14, Diebold et al. disclose a surface roughening step by deposition of colloidal catalyst, such as PdCl<sub>2</sub>-SnCl<sub>2</sub> hydrosol, before deposition of the electrically conducting material. This roughening step is clearly surface morphology-improving step. Further, the colloidal catalyst is inherently non-conducting. Therefore, contrary to applicants' assertion, Diebold et al. clear teach an intervening coat between the electrically conducting material and the substrate.

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In response to applicants' argument that Diebold et al. do not teach that the substrate is "an annealed, preshunk polymeric material", applicants are reminded that Diebold et al. teaches the use of MYLAR<sup>TM</sup> as a substrate (see column 5, lines 62-67). One of ordinary skill in the art would have recognized that MYLAR<sup>TM</sup> is an annealed, preshunk polymeric material.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham, Ph.D., whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.  
December 18, 2000

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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01/12/01